Rec'd 7-7-99

Playtex

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April 13, 1999

Mr. Colin Pollard
Chief of Obstetrics & Gynecological
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Dear Mr. Pollard:

The following is submitted in response to FDA's request for comments on their "Draft Guidance for the Content of Premarket Notifications for Menstrual Tampons" dated May 25, 1995. Because this tampon guidance also is affected by two other final guidance documents that have issued since 1995 ("Deciding When to Submit a 510(k) for a Change to an Existing Device" dated January 10, 1997, hereinafter the "Device Modification Guidance," and "The 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notification" dated March 20, 1998, hereinafter the "510(k) Paradigm Guidance"), we feel it is important that we also address these guidances in our comments.

There have been a significant number of improvements in FDA procedures for submission and review of 510(k) notifications in the last few years due to both formal and informal guidance provided by the Agency. This guidance has led to a much better understanding of content requirements, and, in many instances over the past few years, the FDA has been able to respond to new submissions with a clearance notice in less than 45 days. We believe this time frame is not unreasonable for a thorough review.

In general, we believe that the Agency's May 25, 1995 draft guidance document includes appropriate 510(k) data and information requirements for 510(k)s to support changes to existing tampons and to provide for new product information. The draft guidance appropriately requires a complete description of the tampon, its physical properties, absorbency, material information such as chemical composition of additives or finishing materials etc. In addition, the document provides for safety testing guidelines as may be appropriate to establish the safety of the proposed changes or new materials. The microbiology testing covers the essential details for TSST-1 testing and effects on the vaginal flora. The combination of setting testing standards and monitoring their outcomes has provided the key elements for maximum assurance for safety and effectiveness of tampons.

Our comments are intended to address two areas. One, given that manufacturers now have various options as a result of FDA re-engineering and other initiatives, we request that the Agency clarify in the tampon 510(k) guidance: (a) those changes that do not require a new

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510(k); (b) those changes that require a new 510(k) but which are appropriate for a Special 510(k); and (c) those changes that should proceed through a traditional or abbreviated 510(k) process. Two, we have recommended certain minor revisions to the technical content requirements (which we have set forth in Section B. below).

A. Clarification of Submission Type for Certain Tampon Changes

In the draft May 25, 1995 tampon guidance, the FDA provided certain limited guidance on those "Changes Requiring a 510(k) Submission" and those "Changes Not Requiring a 510(k) Submission." While the list of changes provided in the draft under each category was not intended to be exhaustive, it provided at least some useful guidance to industry. As noted above, since the draft 1995 guidance issued, the Device Modification Guidance referred to in that draft has issued in final, and the FDA has issued its 510(k) Paradigm Guidance, which provides for two other types of 510(k)s: Special 510(k)s and Abbreviated 510(k)s. Accordingly, because the Agency now is preparing to update and revise its draft 1995 tampon guidance, we strongly recommend that the new tampon guidance address the final Device Modification and 510(k) Paradigm Guidance.

In Playtex's view, these guidances have created some confusion for tampon manufacturers regarding what type of 510(k) submission, if any, should be prepared for a particular type of tampon modification. Specifically, for tampons, it is unclear how to distinguish: (1) those types of changes that do not require a new 510(k) from those that are appropriate for a Special 510(k); and (2) those changes that are appropriate for a Special 510(k) from those that require a traditional or abbreviated 510(k). With respect to the first category, for example, the Device Modification Guidance states that a 510(k) is not required for a materials change, if additional biocompatibility testing (as specified in ISO 10993-1) is not required "to assure that a patient would not elicit an undesirable response". The Special 510(k) guidance, however, suggests that a Special 510(k) would be appropriate for a change in material that has been used in other similar legally marketed devices (i.e., where additional biocompatibility testing is not likely required).

Further, the existing overlap between the Special 510(k) and Device Modification Guidance may cause manufacturers to file Special 510(k)s as a form of regulatory precaution, when, in fact, no 510(k) is required. Both processes require use of design controls, including design verification and validation, to demonstrate that acceptance criteria are met. Consequently, because a Special 510(k) requires only limited additional documentation efforts and reduces the regulatory risk, it is possible that tampon manufacturers increasingly will choose to file a Special 510(k) rather than document a "no-510(k)" decision, potentially resulting in a large number of Special 510(k) submissions to the Agency requiring short turn-around review. In Playtex's view, clarification of the types of tampon modifications appropriate for Special 510(k) review would serve to avoid this potential result.

It is also important that the tampon guidance clarify those types of changes that are not appropriate for the Special 510(k) process, and require a traditional or abbreviated 510(k). The 510(k) Paradigm Guidance simply states that Special 510(k)s are not appropriate for modifications that affect the intended use of the device or that have the potential to alter the fundamental scientific technology of the device. For tampons, it is unclear what constitutes the "fundamental scientific technology." In Playtex's view, certain types of design and material changes are not appropriate for Special 510(k) review. Although FDA may not consider these to be "fundamental scientific technology" changes to the device, they constitute significant changes that could potentially affect the performance of the product.

B. Specific Recommendations Regarding Draft 1995 Tampon 510(k) Guidance Requirements

Set forth below are specific recommended revisions to certain sections of the draft 1995 tampon guidance:

1. Device Materials (Section V.A.3.a.) — We recommend that complete chemical and physical specifications only be required for new materials, and that existing materials simply be listed.

2. Dioxin (Section V.A.3.b.) — We recommend that this section be revised as follows:

   > Provide assurance that all tampon pulp-based absorbent materials that are subject to bleaching are derived from Elemental Chlorine-Free (ECF) or Totally Chlorine-Free (TCF) processes.

3. Chemical Composition (Section V.A.3.c.) — We recommend that this section be revised as follows:

   > Provide detailed chemical composition, chemical specifications, and quantity (in ranges/tampon) of finishing and/or anti-wicking agents.

4. Toxicity (Section V.A.4.b.) -- We recommend the following revision:

   > Provide toxicity information on any new additives, such as complete fragrance formulations or deodorant formulations used in the menstrual tampon (i.e., it should not be necessary to evaluate each fragrance ingredient).

5. Clinical Testing (Section V.A.5.) -- We recommend that the second paragraph of this subsection be revised as follows:

Colposcopic exams need not be an absolute requirement, but rather be employed only as deemed necessary by a qualified Principle Investigator, where, in the Investigator's opinion, the changes being evaluated could present significant safety issues that could be addressed by colposcope, and are appropriate to the study design and objectives. Further, colposcopic examination may be conducted by a qualified health care professional.

In Playtex's view, the reference to WHO guidance on conducting pelvic examinations should be deleted. This protocol generally is not considered the standard for such examinations by U.S. medical practitioners and is not generally utilized in the U.S. Attached for your consideration are comments from Mary Jane Minkin M.D., Clinical Professor, Department of Obstetrics and Gynecology, Yale University School of Medicine. Dr. Minkin provides insight on the purposes for which the colposcope is used by practicing gynecologists. She indicates it is primarily used for diagnosing abnormal pap smears.

In closing, I hope our comments are useful. If you have any questions, comments or require further clarification or additional information please contact me directly.

Sincerely,

Mark Rosengarten

cc: Dr. I. Butensky - Playtex Products, Inc.